



UNITED STATES PATENT AND TRADEMARK OFFICE

TC

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,321	05/23/2001	Robert J. Peach	D0028PNP;30436.57USU1	2959

23914 7590 01/29/2004

STEPHEN B. DAVIS
BRISTOL-MYERS SQUIBB COMPANY
PATENT DEPARTMENT
P O BOX 4000
PRINCETON, NJ 08543-4000

EXAMINER

ROARK, JESSICA H

ART UNIT	PAPER NUMBER
----------	--------------

1644

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/865,321

Applicant(s)

PEACH ET AL.

Examiner

Jessica H. Roark

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 67-115 is/are pending in the application.
- 4a) Of the above claim(s) 81-85 and 87-93 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 67-80, 86 and 94-115 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) see OA #3
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1644

DETAILED ACTION

1. Applicant's amendment, filed 11/3/03, is acknowledged.

Claims canceled: 1-66.

Claims added: 97-115.

Claims pending: 67-115.

2. Applicant's election with traverse of Group I in the Paper filed 11/3/03 is acknowledged. The traversal is on the grounds that there is no undue burden to search both Group I and Group II. This is not found persuasive because nucleic acid and protein searches requires review of different databases and the inventions are independent and distinct for the reasons of record.

The requirement is still deemed proper and is therefore made FINAL.

However, it is noted that claim 86 was inadvertently included in Group II in the Restriction Requirement. Claim 86, drawn to a soluble CTLA4 polypeptide, will be examined with Group I.

Claims 81-85 and 87-93 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 67-80, 86 and 94-115 are under consideration in the instant application.

IDS

3. Applicant's IDSs, filed 6/21/01, 1/29/02, 3/12/02, 6/02, 6/14/02, 11/13/02 and 6/25/03 are acknowledged.

It is noted that several duplicate citations have been considered, but line through to prevent printing on the face of any patent that should issue.

In addition, the material filed in the IDS of 11/13/02 has been considered, but lined through as this material is inappropriate for listing on the face of a patent. It is suggested Applicant use the procedure set forth in MPEP 724.02 in the future for filing of proprietary information relevant to the examination.

For Exhibit 57 (Larsen slide presentation, 2000), Applicant should provide the month, day and location of the presentation.

Priority

4. Provisional applications 60/287,576 and 60/214,065 appear to provide adequate written support for the instant claims.

Art Unit: 1644

Specification

5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

It is noted that an amino acid sequence is present in Figure 11 and at numerous locations on page 37 but a Sequence Identifier (SEQ ID NO:9) is not provided. Applicant should amend the specification to include Sequence Identifiers anywhere a sequence appears.

Claim Objections

6. Claim 67 is objected to because of the following informality: the colon is missing following "SEQ ID NO.". Appropriate correction is required.

7. Claim 71 is objected to for the following informality: in the second line, the text "amino acid sequence" is duplicated. Appropriate correction is required.

8. Claims 97-115 are objected to under 37CFR 1.821(d) for failing to recite the SEQ ID NO: in the claims.

Claim Rejections - 35 USC § 112 first paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 86, 94-96 and 115 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

In claims 86, 94-96 and 115, it is apparent that the clone deposited as ATCC No. PTA-2104 is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the pertinent cell lines which produce these antibodies. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, Applicant is required to assure that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications (see 37 CFR 1.808 (a)(2) and MPEP 2410-2410.01).

Although the specification on page 11 at lines 10-13 indicates that Applicant has deposited the clone designated ATCC No. PTA-2104 with the ATCC, there does not appear to be an indication that the Deposit was made under the Budapest Treaty and the assurances mentioned indicated above have not been provided. Applicant's provision of these assurances and a showing that the Deposit was made under the terms of the Budapest Treaty would obviate this objection/rejection.

Art Unit: 1644

Claim Rejections – 35 U.S.C. § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 67-80, 86 and 94-115 are rejected under 35 U.S.C. 102(b) as being anticipated by Peach et al. (WO98/33513, IDS#18, see entire document) *as evidenced by* Cohen et al. (US 2003/0083246 A1).

Peach et al. teach soluble CTLA4 mutant molecules (see entire document, e.g., Abstract).

Peach et al. teach the mutant molecule LEA29Y (page 7, especially lines 26-32). LEA29Y is a soluble CTLA4 mutant molecule which has a higher affinity for CD86 (see Figure 1). Pharmaceutical compositions comprising the mutants are also taught (pages 11-12).

Cohen et al. evidence that LEA29Y is the same molecule as the instant L104EA29YIg mutant whose amino acid sequence is set forth in instant SEQ ID NO:4 and shown in instant Figure 7. In particular, Cohen et al. teach at paragraph 237 that L104EA29YIg is also known as LEA29Y, provide the amino acid sequence of L104EA29YIg in Figure 19, and teach that it is encoded by the nucleic acid deposited as ATCC No. PTA-2104 (see paragraph 84). The amino acid sequence shown in Figure 19 of Cohen et al. is identical to instant SEQ ID NO:4, the amino acid sequence shown in instant Figure 7 and the amino acid sequence encoded by the nucleic acid deposited as ATCC No. PTA-2104.

The Examiner acknowledges that WO98/33513 teaches that the sequence of LEA29Y is set forth in SEQ ID NO:1 (where Xaa is "Y" and Yaa is "E"), and that the amino acid sequence of SEQ ID NO:1 is not the same as instant SEQ ID NO:4 or the amino acid sequence set forth in instant Figure 7.

However, the amino acid sequences provided in WO98/33513 as Figure 7 and SEQ ID NO:1 are inconsistent with the description of the positions mutated in the CTLA4 sequence provided on page 19 of WO98/33513. For example, page 19 identifies the CDR1 loop of CTLA4 as S25 to R33, whereas Figure 7 has S26 and R34. The ordinary artisan at the time the invention was made would therefore have recognized that the numbering and identity of the amino acids mutated to generate the CTLA4 mutant molecules taught by Peach et al. on page 19 of WO98/33513 establish a discrepancy in the sequences set forth in SEQ ID NO:1 and Figure 7 of WO98/33513, particularly in view of the references provided in WO98/33513.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed limitations would be inherent properties of the LEA29Y mutant.

The reference teachings thus appear to anticipate the instant claimed invention.

Applicant is invited to provide evidence that the teachings of WO98/33513 were non-enabling for the instantly recited mutant.

Art Unit: 1644

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 67-80, 86 and 94-115 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26-31 and 34-39 of copending Application No. 09/898195. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of USSN 09/898,195 also teach the same CTLA4 mutant molecule (L104EA29YIg) and pharmaceutical compositions comprising.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 67-80, 86 and 94-115 are directed to an invention not patentably distinct from claims 26-31 and 34-39 of commonly assigned USSN 09/898195 for the reasons set forth supra.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 09/898195, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Art Unit: 1644

Conclusion

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (571) 272-0848. The examiner can normally be reached Monday from 8:30 to 5:00, and Tuesday/Thursday from 10:00 to 4:00. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (571) 272-0841. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number for before Final submissions is (703) 872-9306.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
January 22, 2004

PHILLIP GAMBEL
PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
1/22/04